IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF MARKETING OR ADVERTISING MATERIALS AND CONDUCT AND OTHER LITIGATIONS

Pursuant to the Federal Rules of Evidence, Defendants Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer") respectfully submit this memorandum of law in support of their motion *in limine* to exclude evidence of, and reference to, any marketing, advertising, or promotional materials or conduct concerning Neurontin, or to any other claims, actions, or legal proceedings related to Neurontin.

PRELIMINARY STATEMENT

In this products liability case, Plaintiff will likely seek to introduce, just as plaintiffs have attempted in other Neurontin cases, voluminous and wide-ranging testimonial and documentary evidence relating to Pfizer's marketing and advertising of Neurontin. This evidence should be excluded on multiple grounds, including that it is irrelevant to Plaintiff's failure-to-warn claims, it would unfairly prejudice Pfizer, would confuse the issues for the jury, and would unnecessarily and substantially broaden the scope of this trial.

The MDL court in this litigation dismissed Plaintiff's claims of fraudulent misrepresentation, and upheld Plaintiff's fraudulent concealment claim only to the extent that it is not based on evidence regarding Pfizer's national advertising and marketing campaign. *See In*

re Neurontin Mktg., Sales Practices & Prods. Liab. Litig., 618 F. Supp. 2d 96, 114 (D. Mass. 2009) ("*Neurontin III*"). Likewise, the MDL court also repeatedly recognized that off-label promotion does not constitute fraud, much less the narrow fraud by omission claim that was allowed to proceed. *See, e.g.*, *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 257 F.R.D. 315, 329 (D. Mass. 2009) ("*Neurontin II*"); *In re Neurontin Mktg. & Sales Practices Litig.*, 244 F.R.D. 89, 92 n.6 (D. Mass 2007) ("*Neurontin I*"). These rulings confirm that evidence and testimony regarding national advertising and marketing of Neurontin is wholly irrelevant to Plaintiff's claims and should be excluded.

Moreover, none of Plaintiff's marketing evidence bears any connection to Decedent, Richard Smith, or the actions of his prescribing healthcare providers. None of it relates in any way to the issues for the jury to decide at Plaintiff's trial: whether Neurontin causes suicidal behavior; whether Neurontin's label contained adequate warnings in 2004; whether Mr. Smith was using Neurontin at the time of his death; and whether Mr. Smith's decision to take his own life resulted from his use of Neurontin or from his many other well-accepted risk factors for suicide.

For similar reasons, the Court should exclude any other claims, actions, or legal proceedings related to Neurontin. Such evidence is irrelevant to this case and would unfairly prejudice Pfizer. No other similar Neurontin lawsuit has been tried to judgment, these suits offer only allegations, not evidence, and are both irrelevant and inadmissible hearsay.[1] As such, evidence of these other proceedings would unfairly prejudice Pfizer by suggesting that the jury impose liability for improper reasons.

The evidence that is the subject of this motion would serve only to influence the jury to

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[1] In March 2010, a jury verdict was rendered in the case of *Kaiser Foundation Health Plan, et al. v. Pfizer, Inc., et al.* Judgment has not yet been entered in that action and the time for post-trial motions and appeal has not passed. Moreover, the lawsuit was not a personal injury or wrongful death lawsuit and the verdict did not address the adequacy of Neurontin's label. The *Kaiser* verdict is, therefore, completely irrelevant to this case and would be introduced solely for the purpose of improperly prejudicing the jury. In addition, as discussed below, courts routinely exclude evidence of other litigation, even where cases are tried to judgment.

reach the wholly irrelevant, but highly prejudicial, conclusion that Pfizer engaged in improper marketing and is a "bad actor."[2] The Rules and the case law mandate that all such evidence be excluded.

ARGUMENT

I. EVIDENCE OF PFIZER'S MARKETING OR ADVERTISING OF NEURONTIN SHOULD BE EXCLUDED AS IRRELEVANT

Plaintiff has designated as trial exhibits evidence pertaining to national (and in some cases, foreign) marketing and advertising activities that are unrelated to the facts and issues in this case. For example, here, as in the last two product liability cases to go to trial – *Bulger v. Pfizer* and *Shearer v. Pfizer* – Plaintiff's exhibit list includes evidence relating to: speaker bureau presentations; continuing medical education presentations; consultants' meetings; advisory board meetings; teleconferences; Pfizer's involvement in the publication of clinical trial and study results; correspondence with the FDA regarding promotional pieces; and internal communications regarding the marketing and promotion of Neurontin, all of which are completely unconnected to the decisions of Mr. Smith's healthcare providers to prescribe Neurontin to him. Also, as in previous cases, Plaintiff has designated numerous witnesses by deposition (and likely will also bring certain witnesses live), whose testimony pertains only to national marketing and is not relevant to the issues in this case, including: David Franklin (plaintiff-relator in *Franklin*),[3] Helen Duda-Racki, Bruce Fleischman, John Knoop, John Marino, Avanish Mishra, Charles King, and Martin Teicher.

Under Tennessee's "learned intermediary doctrine," a prescription drug manufacturer fulfills its duty to warn "by providing the physician with adequate warnings of the risks

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[2] As this Court is aware, Warner-Lambert pleaded guilty in 2004 to strict liability violations of the Federal Food, Drug, and Cosmetic Act relating to specific instances of marketing of Neurontin for off-label uses in 1995 and 1996, several years before Mr. Smith was ever prescribed Neurontin. The guilty plea and related evidence are subject to a separate motion *in limine*, filed concurrently herewith, and incorporated herein by reference. Pfizer also incorporates its separate motions *in limine* with regard to evidence related to Charles King and David Franklin (plaintiff-relator in *Franklin*).

[3] Mr. Franklin's testimony is the subject of a separate motion to exclude, filed concurrently herewith and incorporated by reference.

associated with the use of its drug." *Pittman ex rel. v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994). As the MDL court has already found in dismissing Plaintiff's claims of affirmative fraudulent misrepresentation, Plaintiff has not even alleged, much less proffered evidence, that Mr. Smith's prescribing healthcare providers relied upon any marketing materials or statements by Pfizer concerning Neurontin in making their prescribing decisions in Mr. Smith's case. *See Neurontin III*, 618 F. Supp. 2d at 112. To the contrary, neither Dr. Mackey nor Nurse Krancer[4] recalled receiving any particular promotional statements by Pfizer that they relied upon in prescribing Neurontin to Mr. Smith. (Ex. A, Mackey Dep. at 76:2-77:23; Ex. B, Krancer Dep. at 31:10-24.)

Advertising and promotional statements are thus completely irrelevant to the question of whether Pfizer's labeling for Neurontin adequately warned of its known risks and whether any additional suicide warning would have changed their decisions to prescribe Neurontin to Mr. Smith. *See, e.g.*, *In re Norplant Contraceptive Prods. Liab. Litig.*, No. MDL 1038, 1997 WL 81092, at *1 (E.D. Tex. Feb. 21, 1997) (observing that a determination of whether a physician was adequately warned involves a consideration of "all materials to which the physician was actually exposed, including patient materials . . . as well as advertisements actually *seen* by the physician" and excluding evidence of marketing and promotional materials and correspondence where there was no evidence that plaintiff's prescribers were exposed to such evidence (emphasis added)); *see also In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 223140, at *5 (M.D. Fla. Jan. 30) (excluding letters from FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") because "[p]laintiffs [had] not shown that their prescribing physicians were exposed to the promotional materials" at issue in the letters), *aff'd*, 601 F. Supp. 2d 1313 (M.D. Fla. 2009); *Miller v. Pfizer Inc (Roerig Div.)*, 196 F. Supp. 2d 1095, 1122-23 (D. Kan. 2002) (granting summary judgment because plaintiff

[4] Plaintiff also makes allegations regarding Dr. Paul McCombs, III, but it is undisputed that Mr. Smith did not fill or take any Neurontin prescription written by Dr. McCombs. (*See* Ex. C, Ruth Smith Dep. at 112:13-117:15.)

provided no evidence that plaintiff's physician relied on representations by manufacturer), *aff'd*, 356 F.3d 1326 (10th Cir. 2004); *Alexander v. Smith & Nephew, P.L.C.*, 90 F. Supp. 2d 1225, 1235-36 (N.D. Okla. 2000) (same); *Zampirri v. Acromed Corp.* (*In re Orthopedic Bone Screw Prods. Liab. Litig.*), No. 93-7074, 1995 WL 273597, at *11 n.13 (E.D. Pa. Feb. 22, 1995) (holding that plaintiff bears the burden of showing that defendant promoted or marketed its device to a particular physician and that such promotion caused the doctor to use the device). Marketing evidence is similarly irrelevant to the questions of whether Neurontin is scientifically capable of inducing suicidal behavior, whether, at the time Neurontin was prescribed to Mr. Smith, Neurontin's label contained adequate warnings, whether Mr. Smith was taking Neurontin at the time of his death, and whether Mr. Smith's suicide was caused by Neurontin.

Nor is such evidence relevant to Plaintiff's fraud by omission claim. As the MDL court has recognized, off-label marketing, even if it occurred, is not itself fraudulent: "While off-label marketing is illegal, there is no private right of action to enforce it. To succeed on their claims, plaintiffs must prove that defendants' representations were false, along with all other elements of their claims." *Neurontin I*, 244 F.R.D. at 92 n.6 (citation omitted); *see also Neurontin II*, 257 F.R.D. at 329 (holding that consumer plaintiffs must establish that "defendants' *fraudulent* marketing, not simply their off-label marketing, caused the prescriptions written for the putative class members"). And, as noted above, Plaintiff's claims of fraudulent omission cannot be based upon omissions from national marketing. *Neurontin III*, 618 F. Supp. 2d at 114.

Plaintiff may argue that off-label marketing is relevant to the issue of duty. However, those courts that have recognized a duty to warn of risks associated with off-label use have done so based upon the *foreseeability* of the off-label use, not whether the drug was *marketed* for off-label uses. *See McNeil v. Wyeth*, 462 F.3d 364, 369 (5th Cir. 2006); *Woodbury v. Janssen Pharmaceutica, Inc.*, No. 93 C 7118, 1997 WL 201571, at *9 (N.D. Ill. Apr. 10, 1997); *cf. Pittman*, 890 S.W.2d at 428-29 (holding that the manufacturer of a prescription drug has a duty to warn of the risks associated with foreseeable misuses). In other words, the duty derives from a manufacturer's duty to warn of risks associated with foreseeable misuses of a product. *See*

Pittman, 890 S.W.2d at 429 (holding that the warning accompanying a prescription drug "must reasonably communicate" harm that could result from misuse of the drug (citation omitted)). In this case, Pfizer admits that it was aware that Neurontin was being prescribed off-label, including for general neuropathic pain. Pfizer does not contend that the prescription of Neurontin to treat Mr. Smith's pain was unforeseeable or that it constituted a misuse of the product. To the contrary, Pfizer has consistently maintained in this litigation that physicians were entitled to exercise their independent medical judgment and prescribe Neurontin for off-label uses. Pfizer argues that there was no duty to warn of the risk of suicide not because *off-label uses* were unforeseeable, but because the *risk* was unforeseeable. That is, Pfizer argues that there was no duty to warn because there was not at the time of Mr. Smith's death any reliable evidence establishing a causal association between Neurontin and suicide. This is true regardless of whether Neurontin was prescribed for a labeled or off-label use.

Accordingly, because the foreseeability of off-label use is not at issue in this litigation, Plaintiff's proffered evidence in support of her allegations regarding Defendants' marketing of Neurontin for off-label use is not probative of any relevant and material fact. Plaintiff cannot introduce otherwise irrelevant evidence to prove an issue that has no bearing on the outcome of this case. *See, e.g.*, *Turner v. Allstate Ins. Co.*, 902 F.2d 1208, 1212-13 (6th Cir. 1990) (ruling inadmissible evidence offered to show a party's good faith when the issue of good faith was not disputed).

II. ANY PROBATIVE VALUE OF MARKETING EVIDENCE IS SUBSTANTIALLY OUTWEIGHED BY ITS POTENTIAL FOR UNFAIR PREJUDICE, CONFUSION OF THE ISSUES, AND WASTE OF TIME

Even if marketing evidence had some marginal relevance for a permissible purpose, which it does not, it should be excluded pursuant to Rule 403 because "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, [and] misleading the jury" and by undue delay and waste of time. Fed. R. Evid. 403. Specifically, because it is clear that marketing materials played no causal role in this case, their introduction would serve only to encourage a jury to base its decision not on the facts properly before it but

on the basis of inflammatory allegations against Pfizer that are unrelated to the issues in this case. This is precisely the sort of prejudice at which Rule 403 is aimed.

Further, the introduction of marketing evidence will substantially, and unnecessarily, prolong this trial and doubtlessly transform this product liability case into a trial about the irrelevant but complex regulatory regime regarding prescription drug promotion. To respond to the types of attacks Pfizer anticipates Plaintiff will attempt through marketing evidence, Pfizer would need to present responsive evidence. In the case of unimplemented marketing activities, for example, Pfizer would need to waste valuable trial time eliciting evidence that makes clear that they were never implemented and never affected any prescription decision, much less those at issue in the case. Jurors will likely become confused and may be misled into thinking that Pfizer is on trial for its promotion of Neurontin, rather than for an alleged failure to warn of a safety risk. Letters issued by DDMAC, though unrelated to the claims at issue here, may further distract the jurors from the real issues at trial by focusing needlessly on Pfizer's promotional activity. The Court should not permit this irrelevant, time-consuming "trial within a trial" and should instead focus the jury on Plaintiff's claim for failure to warn by excluding marketing evidence.

III. MARKETING EVIDENCE CONSTITUTES IMPERMISSIBLE CHARACTER PROPENSITY EVIDENCE AND SHOULD THEREFORE BE EXCLUDED UNDER RULE 404(B)

Given the lack of relevance of marketing evidence to this case, the only conceivable use for which Plaintiff would seek to have it admitted would be to attempt to impugn Pfizer's character, in violation of Rule 404(b). Plaintiff will seek to portray Pfizer as a "bad actor" in the most general sense by trying to convince a jury that Pfizer has illegally, fraudulently, or otherwise improperly promoted Neurontin. The Sixth Circuit has held that a proponent of prior bad acts evidence must establish four requirements:

> (1) the evidence must be directed toward establishing something other than a party's propensity to commit the act charged; (2) the other act must be similar enough and close enough in time to be relevant to the matter at issue; (3) the evidence must be such that the jury could find that the act occurred and that the

> party in question committed it; and (4) the prejudicial effect of the evidence must not clearly outweigh its probative value.

McLeod v. Parsons Corp., 73 F. App'x 846, 854 (6th Cir. 2003) (citations omitted). As established above, Plaintiff cannot meet these requirements because marketing evidence is irrelevant to this dispute and will cause unfair prejudice and undue delay. While Rule 404(b) allows the introduction of other crimes, wrongs, or acts for certain purposes such as "proof of motive, opportunity, intent, preparation, plan, knowledge, identity, or absence of mistake or accident," no such alternate reason has or could be proffered in the instant case. Fed. R. Evid. 404(b). The only possible use of marketing evidence is specifically precluded by Rule 404(b): to invite the jury to base a finding of liability on Pfizer's alleged character rather than on the merits of Plaintiff's product liability allegations.

Plaintiff may try to fit irrelevant marketing evidence within one of Rule 404(b)'s exceptions, most likely motive or intent. However, courts have made clear that the exceptions must be narrowly construed so that the prohibition against character evidence is not reduced to a hollow pronouncement. "[T]he analysis required under Fed. R. Evid. 404(b) must be more than merely inquiring if an exception is applicable and then automatically allowing in all evidence that seemingly fits into the exception. . . . The Court therefore views its role as one of a 'gate-keeper' similar to the non-involved role that judges have with respect to expert witnesses." *United States v. Gerard*, 926 F. Supp. 1351, 1358 (N.D. Ill. 1996) (citation omitted), *aff'd mem.*, 129 F.3d 119 (7th Cir. 1997). Thus, to escape the "absolute bar" of Rule 404(b), the proponent must show a "clear nexus between" the evidence and a specific, disputed consequential fact in the litigation by an evidential theory that does not rely on any inference about the defendant's propensity or character. *McLeod*, 73 F. App'x at 854; *see also United States v. Varoudakis*, 233 F.3d 113, 125 n.11 (1st Cir. 2000) (reversing conviction based upon admission of prior bad acts and cautioning that Rule 404(b)'s "exceptions must not swallow the rule").

For example, courts have repeatedly held that Rule 404(b) does not permit evidence of prior alleged bad acts in order to show *generalized intent* to commit the act at issue in the

litigation. *See, e.g.*, *Fisher v. Am. Gen. Fin. Co.*, 52 F. App'x 601, 606-07 & n.3 (4th Cir. 2002) (per curiam) (evidence that defendant's employees routinely fabricated personal property descriptions on loan applications was relevant only of a generalized intent to commit dishonest acts and, therefore, inadmissible under Federal Rule of Evidence 404(b)); *Crawford v. Yellow Cab Co.*, 572 F. Supp. 1205, 1208-09 (N.D. Ill. 1983) (rejecting argument that evidence of other bad acts was admissible to prove that the defendant's actions were "consistent with its corporate practice and policy of indifference to the duty to safely entrust vehicles").

As the Third Circuit has explained, "'a proponent's incantation of the proper uses of [Rule 404(b) evidence] . . . does not magically transform inadmissible evidence into admissible evidence.'" *Becker v. ARCO Chem. Co.*, 207 F.3d 176, 191 (3d Cir. 2000) (citation omitted) (alteration in original). Rather, the relevance of the evidence must be established by linking logical inferences to the specific facts at issue in the lawsuit. *See McLeod*, 73 F. App'x at 854 (excluding evidence under Rule 404(b) because proponent failed to show a "clear nexus between" the evidence and the facts of the case). At no point can one of the links be that the defendant had the propensity to act a certain way. *See Becker*, 207 F.3d at 191.

Thus, when offered only to show bad character of the defendant, even if that character might be characterized as a "motive," the evidence is inadmissible. *See, e.g.*, *Jankins v. TDC Mgmt. Corp.*, 21 F.3d 436, 441 (D.C. Cir. 1994) (holding that prior conduct evidence proffered to demonstrate, *inter alia*, greed, inadmissible under Rule 404(b) because it was "only a shade less general than a claim that [the defendant] was a bad man"). In this case, evidence of certain promotional activities years before Mr. Smith was ever prescribed Neurontin (and in an entirely different geographical region) could never be probative of any of the elements that Plaintiff must prove and the exceptions listed in Rule 404(b) cannot be used as an end-run around the general prohibition against character evidence. *See McLeod*, 73 F. App'x at 854 (holding that the proponent must show the proffered evidence was "similar enough and close enough in time to be relevant to the matter at issue").

IV. EVIDENCE OF OTHER CLAIMS, ACTIONS, OR PROCEEDINGS RELATED TO NEURONTIN IS LIKEWISE INADMISSIBLE

To the extent that Plaintiff seeks to advise the jury, through argument or evidence, that other Neurontin lawsuits have been filed against Pfizer, such evidence is wholly irrelevant and could be offered only to induce the juror to render a verdict on an improper basis. Initially, evidence of non-product liability litigation in which the plaintiffs sought to recover amounts paid for Neurontin prescriptions based upon alleged improper marketing are irrelevant and prejudicial for the reasons stated in Sections I through III above.

Moreover, the fact that other lawsuits have been filed, or claims have been made, against Pfizer means, at most, that others have made allegations against Pfizer. Allegations, however, are not evidence, and, if offered to prove the truth of the matter asserted – generic causation or failure to warn – are hearsay for which there is no exception. *See, e.g.*, *Olson v. Ford Motor Co.*, 410 F. Supp. 2d 855, 861 (D.N.D. 2006); *Boston Beverage Corp. v. Turner*, 81 B.R. 738, 747 (D. Mass. 1987). In fact, even if another lawsuit is tried and the jury finds for the plaintiff, the jury verdict is inadmissible hearsay. *See* Fed. R. Evid. 803(22) (hearsay exception for judgments in other cases applies only to criminal felony cases). As a result, courts have been unwilling to admit even judgments from previous cases. *See, e.g.*, *Greycas, Inc. v. Proud,* 826 F.2d 1560, 1567 (7th Cir. 1987); *Colonial Refrigerated Transp., Inc. v. Mitchell*, 403 F.2d 541, 551 (5th Cir. 1968).

In addition, courts have recognized that, even when other claims and lawsuits have been proffered on the issue of notice, the prejudicial value of the evidence outweighs any probative value. *See, e.g.*, *McLeod v. Parsons Corp.*, 73 F. App'x 846, 853-54 (6th Cir. 2003) (affirming trial court's decision to exclude as irrelevant evidence of other unrelated lawsuits against defendant); *CPC Int'l, Inc. v. Northbrook Excess & Surplus Ins. Co.*, 144 F.3d 35, 45 (1st Cir. 1998) (in environmental insurance action, affirming exclusion of evidence of prior judicial findings of environmental contamination by defendant because of the danger that such evidence could "lead to a decision based on emotion or a desire to punish"); *Kinan v. City of Brockton*,

876 F.2d 1029, 1034-35 (1st Cir. 1989) (affirming exclusion of evidence of two previous civil rights cases filed against defendant because their remote relevancy was outweighed by the potential for prejudice); *Barnes v. Koppers, Inc.*, No. 3:03CV60-P-D, 2006 WL 940279, at *3 (N.D. Miss. Apr. 11, 2006) (holding that "evidence of other lawsuits, claims, and injuries" even in same geographical area was "irrelevant to this case and therefore inadmissible"); *Grant Thornton, LLP v. FDIC*, No. 1:00-655, 2007 WL 518421, at *1 (S.D. W. Va. Feb. 13, 2007) ("Allowing evidence of other litigation [against plaintiff] would not only cause the issues of the current case to be delayed . . . but would confuse the issues by introducing twelve additional fact situations which would have to be dealt with individually before a decision on the merits of the current case could be reached.").

In this case, no conceivable argument for the relevance of such evidence can be offered by Plaintiff. No similar Neurontin case has been tried to judgment,[5] and no determination of causation has been made in any such litigation. Even if there were a verdict, the plaintiffs or decedents in other Neurontin lawsuits differ significantly from Mr. Smith in myriad ways, including dose and duration of use of Neurontin, health and mental health history, concurrent medications, other risk factors for suicide, alleged injuries and, perhaps most importantly, the prescribing healthcare providers' knowledge, decision-making, and directions to the patient.

CONCLUSION

For the reasons set forth above, Defendants respectfully request that the Court exclude at trial any and all evidence relating to Pfizer's marketing of Neurontin and evidence of other litigations.

[5] *See supra* at fn. 1.

Dated: April 16, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 16th day of April 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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